APF Calls for Balanced Perspective on FDA's Proposed Risk Evaluation Mitigation Strategy (REMS) for Opioid Therapy

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As the largest organization in the United States to focus on the rights of people with pain, the American Pain Foundation has serious concerns about the direction that the U.S. Food and Drug Administration (FDA) is taking regarding the development of REMS for opioids. Together, in an ambitious collaborative effort within the Pain Care Forum (PCF), we have worked tirelessly to create recommendations for the FDA regarding an all class REMS. Our hope is that the contribution of best thinking around this issue will result in a rational and fair solution for a most complex problem. Knowing that the abuse and misuse of opioid medicines is a serious public safety concern with devastating consequences, approaches to mitigating this abuse must be balanced with the fact that there are millions of Americans who rely upon prescription opioid medication in order to get up each morning and face their day with some semblance of worth and dignity. The FDA solution must not cause harm to one substantially larger group of Americans in order to attempt to protect another group from harm.

Recommendations for an Opioid REMS were developed by the Pain Care Forum, a broad-based coalition of 48 organizations who are devoted to the relief of pain. These organizations range from non-profit consumer education, advocacy, policy, medical services, industry, ethics and professional associations. APF endorses the recommendations made in this document which has been submitted to the FDA for the record. One aspect we strongly support is regarding public education efforts. The need to focus on the safe use, safe storage and safe disposal of medicines to prevent prescription opioid medication from entering illicit channels of distribution is a reasonable educational solution. APF does not and will not endorse restrictive, punitive systems such as patient "registries" which further stigmatize people with pain, create additional hardships and new barriers to effective pain care which will have devastating consequences.

Additionally, there is NO reliable data that clearly explains the intersection of opioid drug abuse and those prescribing, dispensing or receiving opioids for legitimate medical use. Better research that includes improved surveillance data is needed. National Institute on Drug Abuse (NIDA) and Substance Abuse Mental Health Services Administration (SAMHSA) surveys are not providing a clear sense of the root cause. Outcome monitoring cannot be established for any REMS if the problem is not well understood. APF heeds the FDA to go slowly as this effort is moved forward. Piloting a newly-developed REMS program is clearly warranted. Do not cause more harm to those who live with pain by impeding their access to the very medication class and formulation that allows them to live a quality life.

People *living with pain* wish for a life worth living, one that permits them to enjoy their family and friends, as well as contribute to our economy. The cost of pain not only includes direct costs associated with doctor's visits, diagnostics and medication, but indirect costs such as lost wages and productivity, of people with pain as well as family members and caregivers. Aside from stealing livelihoods, untreated pain has been shown to shorten the lives of those who suffer. Some, who no longer consider their lives worth living, see suicide as their only option. These lives and livelihoods lost to pain are worth **no less** than victims of drug misuse or abuse.

Alleviating pain is a medical imperative. Opioid medications play a crucial role in a multi-modality approach to treating pain for millions. Fears about opioid abuse and misuse cannot overshadow the stories of people with pain whose lives were once shattered by relentless pain but are now receiving deserving relief from legally prescribed opioid medications. On behalf of these individuals and their families, the American Pain Foundation, along with the Pain Care Forum, implores the FDA to listen to their voices while finalizing an equitable REMS solution.